Medical Device Requirements, Human Factors, and the FDA

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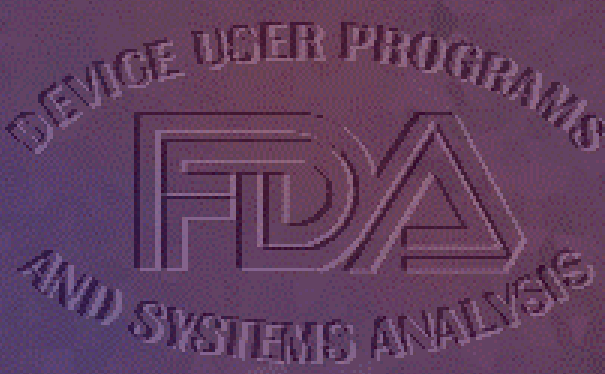
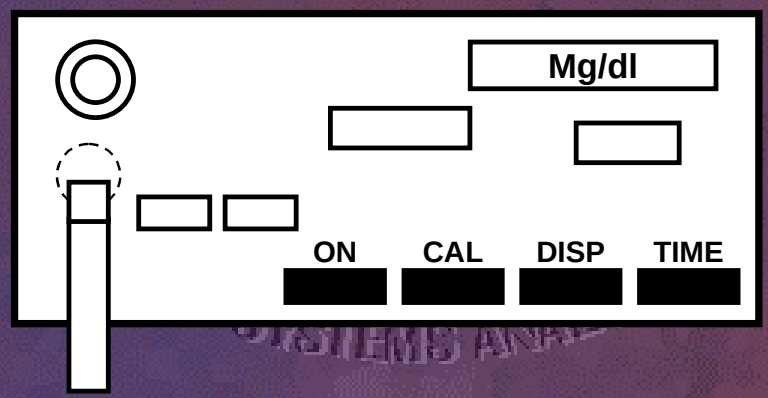


Scope

- Large manufacturing community (10,000 - 15,000 companies).
- CDRH staff @ 950.
- Huge range of medical devices.



Regulations & Design

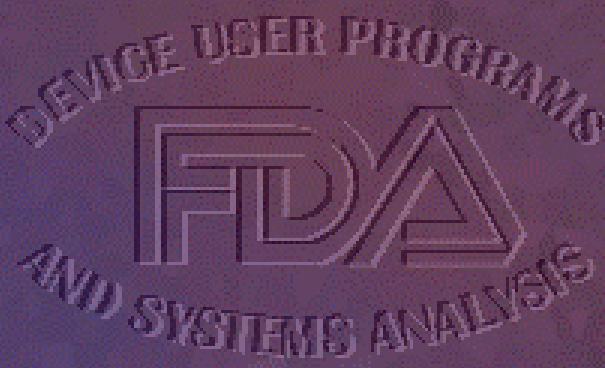
- Until recently, no regulatory power

  -- but recent changes --

- Safe Medical Devices Act, 1990
- Quality Systems Regulation, 1996 (Design Controls - June, 1997)

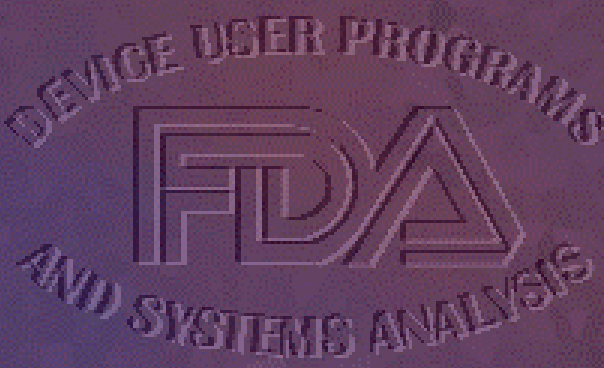
Design Controls

- Regulatory Language:
  - "…design requirements … intended use … needs of the user and patient."
  - "… testing production units under actual or simulated use conditions."



Design Controls

- Preamble Language:
  - "…conduct appropriate human factors studies, analyses, and tests …"
  - "… human interface includes both the hardware and software characteristics…"



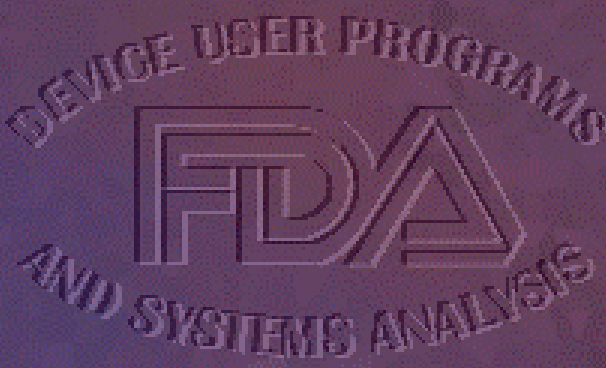
Impacts of Regulatory Change

- Field Inspections - Are there systematic design procedures in place?
- Device Reviews - What are the design issues? -- What does the data look like?
- Post-market Surveillance - What are the design implications of device incidents?

Human Factors Program Historically

In the past, HF projects focused on:

- labeling,
- user training &,
- research.



Current Human Factors Program

- Design Emphasis
- Guidance Development
- HF Education
- Technical Support
- Outside Meetings, Collaborative Projects, and Articles
- Standards Development

Guidance

- Two primary guidance documents- "*Do It By Design" (1996)* & "*Medical Device Use-Safety: Incorporating Human Factors Engineering Into Risk Management", (2000)*
- HF integrated into pre-market & post-market guidance documents

Education

Methods

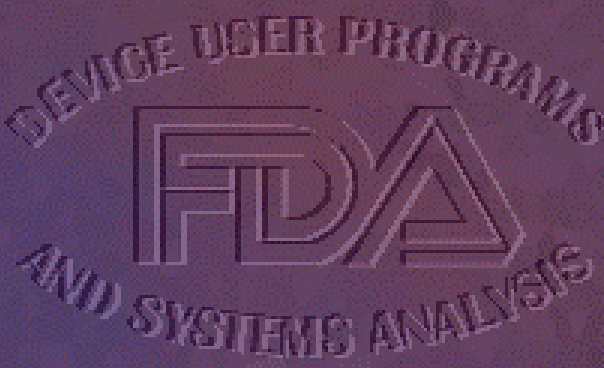
- Lectures, tapes, computer-based training, & teleconferences

Target Audiences

- Field investigators/inspectors, device reviewers, analysts, & manufacturers

Technical support

- Pre-market reviews
- Post-market analysis



Meetings, Collaborative Efforts, Publications, etc.

- Cooperative projects with industry & health organizations
- Industry, health professional, and HF meetings
- Articles and public information

Outlook

- Incident reporting - major challenge
- FDA - steadily increasing focus on HF design.
- Industry response - greater awareness; increasing efforts.